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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/740,486

12/19/2000

Alan S. Waggoner

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 03/17/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/740,486

Applicant(s)
Waggoner

Examiner
Padmashri Ponnaluri

Art Unit
1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 12, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-24 is/are pending in the application.
- 4a) Of the above, claim(s) 9-12, 15, 19, and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 14, 16-18, and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16 6) ☐ Other:

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DETAILED ACTION

NOTE: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1639.

1. Applicants response and amendment filed on 12/12/02 have been considered and entered into the application.
2. Claims 9-24 are currently pending in this application.
3. Claims 9-12, and 21-24 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 10.
4. Claims 15 and 19 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected species invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 10.
5. This application contains claims 8-12, 15, 19, 21-24 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CAR 1.144) See MPEP § 821.01.
6. Claims 13-14, 16-18 and 20 are currently being examined in this application.

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7. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

8. The information disclosure statement filed on 10/16/02 has not been considered because later filed Information Disclosure Statement (filed on 11/13/02) requested to ignore the IDS filed on 10/16/02.

9. The references by Ficken (1971), and Neblette; and 1-239548 (Japan), 6-122696 (Japan) in the information disclosure statement filed on 11/13/02 fails to comply with the provisions of 37 CAR 1.97, 1.98 and MPEP § 609 because Ficken et al do not recite the page numbers and Neblette reference does not provide date of the publication; and the no English language translations for the Japanese application were not provided. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CAR 1.97(e). See MPEP § 609 C(1).

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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11. The rejection of claims 17-18 and 20 under 35 U.S.C. 102(b) as being anticipated by either US Patent 4,404,289 (MASUDA et al) or US Patent 4,405,711 (MASUDA et al) is maintained for the reasons set forth in the previous office action mailed on 8/16/02..

12. The rejection of claims 17-18, 20 under 35 U.S.C. 102(b) as being anticipated by Waggoner et al (Biophysical Journal, vol. 33, 1981, page 292a) is maintained for the reasons set forth in the previous office action mailed on 8/16/02.

13. The obviousness-type double patenting rejection of claims 13-14, 16-18 and 20 over claims 1-11 of U.S. Patent No. 6,225,050 is maintained for the reasons set forth in the previous office action mailed on 8/16/02..

14. The obviousness-type double patenting rejection of claims 13-14, 16-18 and 20 over claims 1-10 of U.S. Patent No. 5,627,027 is maintained for the reasons set forth in the previous office action mailed on 8/16/02.

15. The obviousness-type double patenting rejection of claims 13-14, 16-18 and 20 over claims 1-9 of U.S. Patent No. 5,569,766 is maintained for the reasons set forth in the previous office action mailed on 8/16/02.

Response to Arguments

16. Applicant's arguments filed on 12/12/02 regarding the rejection of claims over US Patents 4,404,289 (the '289 patent) and 4,405,711 (the '711 patent) have been fully considered but they are not persuasive.

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Masuda et al (the '289 patent) disclose methods for immunochemical measurement of trace component. The reference discloses that the antigen or antibody (refers to protein) labeled with spectral sensitizers such as cyanine dyes of formula C (i.e., see column 10). The reference discloses that the disclosed spectral sensitizers are particularly advantageous as the labeling substances since these dyes are excellent in binding to the trace components such as antigen or antibody. The reference discloses the formula of the cyanine dye of formula C in columns 11-13. The reference clearly anticipates the claimed invention.

Masuda et al (the '711 patent) discloses a method of assay for a trace component such as antigen, antibody or enzyme utilizing immunochemical reaction or enzyme reaction in combination with photographic detection system comprising optical density. The reference discloses that the spectral sensitizer employed for labeling a trace component such as antigen or antibody or synthetic substrate, include cyanine dyes (i.e., see column 10). The reference clearly anticipates the claimed invention.

Applicants argue that either the '289 patent and the '711 patent do not teach the instant claim methods. Applicants argue that the patents relate to materials used as spectral sensitizers for photographic use to label trace components such as an antigen or antibody.

Applicants arguments have been considered but are not persuasive. The instant claims are drawn to products not to the methods. The 289 patent and the '711 patent disclose antigen or antibody labeled with spectral sensitizers. Thus the reference antigen or antibody labeled with spectral sensitizers read on the instant claim products. The reference teaches Cyanine dyes of

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formula C and water is used as solvent in labeling, read on the cyanine dye in aqueous liquid of the instant claims.

In response to applicant's argument that 'detectable by luminescence', a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 U. S. P. Q. 235 (CCPA 1967) and In re Otto, 136 U. S. P. Q. 458, 459 (CCPA 1963).

If applicants disagree that the 'luminescent dyes' are structurally different from the 'sensitizers' applicants are requested to include the structural limitations into the claims.

17.

Applicant's arguments filed on 12/12/02 regarding the rejection of claims over Waggoner et al (Biophysical Journal, vol. 33, 1981, page 292a) have been fully considered but they are not persuasive.

Waggoner et al disclose that the reactive sulfhydryl group on the F1 region of cattle rhodopsin has been covalently labeled with a cyanine dye. The absorption of the dye at 660 nm is sensitive to conformational changes of rhodopsin that occur following a short and intense light flash. Thus the reference clearly anticipates the claimed invention.

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*Applicants argue that Waggoner et al disclose reactive sulfhydryl group on the F1 region of the cattle rhodopsin has been covalently labeled with a cyanine dye. **The precise structural features of the cyanine dye used to label this molecule are not specified.***

Applicants arguments have been considered but are not persuasive. The instant claims are drawn to 'a luminescently labeled component of an aqueous liquid comprising a luminescent dye from the group consisting of cyanine containing at least one sulphonate group and said dye reactive with and bound to said component....'.

The reference rhodopsin reads on the instant claim component, and the cyanine dye of the reference reads on the instant claim dye; and the component (rhodopsin) is labeled with the dye. Thus the reference clearly anticipates the claimed product.

*Applicants further argue that the reference '...does not disclose that the dye selected from the group consisting of cyanine merocyanine and styryl dye must contain at least one sulphonate or sulphonic acid group. ' Applicants arguments have been considered but are not persuasive, because the instant claim 17 recites "...selected from the group consisting of cyanine, merocyanine and styryl dyes (**considered as cyanine or merocyanine or styryldyes**) containing at least one sulphonate or sulphonic acid attached to an aromatic nucleus...." Thus the instant claim dye is not cyanine merocyanine dye as in the applicants arguments. Further applicants if argue that the cyanine dye taught by the reference is not same as the instant claimed cyanine dye, applicants are requested to show structurally how the cyanine dyes of the reference would not read on the cyanine dye used in the instant claimed composition.*

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Applicants further argue that claim 20 relates to a protein, nucleic acid, cell, sugar or carbohydrate having an amino or hydroxyl group labeled with a luminescent cyanine dye. Applicants assert that the claimed composition is novel. Applicants arguments have been considered but are not persuasive, because the reference teaches rhodopsin has been covalently labeled with a cyanine dye. Applicants argue that the reference does not disclose a compound with amino or hydroxy group which is labeled with cyanine dye. Applicants arguments have been considered, however the reference teaches rhodopsin labeled with cyanine dye. If applicants argue that the hydroxy or amino group of the protein is labeled with the cyanine dye, Applicants are requested to amend the claim. The instant claim is interpreted as a protein labeled with cyanine dye. The rejections of record have been maintained for the reasons of record.

Applicants argue that the reference does not teach that the labeled composition in liquid. Waggoner et al disclose that '...detergent solution (refers to the aqueous liquid of the instant claims) of rhodopsindifferent kinetics at the labeled site...' . thus the reference composition is in liquid. And applicants arguments that the reference does not teach sulphonic acid or sulphonate group attached to an aromatic nucleus. Examiner agrees with applicants that Waggoner et al has not specifically teach the use of cyanine dyes which have sulphonate group attached to the aromatic ring. However, the sulfonated cyanine dyes are well known in the art and they are particularly useful in since they are highly soluble in water. Thus, even though the reference does not specifically define the structure of the cyanine dye used in labeling, the features are inherent of the dye.

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Applicants further argue the advantages of the attaching sulphonate or sulphonic acid group to the aromatic nuclei of cyanine dye. However, since the advantages of sulphonation of cyanine dyes was well known in the art. Applicants arguments are not persuasive. Thus rejections of record have been maintained for the reasons of record.

18. Applicant's arguments filed on 12/12/02 regarding the obviousness-type double patenting rejections have been fully considered but they are not persuasive. Applicants have requested to withhold the rejection in abeyance until other issues are resolved and the claims found allowable. Thus, the rejections of record have been maintained for the reasons of record in the absence of terminal disclaimer filed.

New Rejections necessitated by the filing of Information Disclosure

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 17-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent GB 1529202A (provided by applicants in IDS filed on 11/13/02)..

The GB 1529202 Patent (the GB '202 patent) teaches novel spectral sensitizing dyes. The spectral sensitizing dinuclear cyanine dye or merocyanine dye which has attached either to a heterocyclic nucleus of the dye to the methine chain of the dye with hydrophilic colloidal which

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contains SH-, NH₂-, NH=, OH- groups. The reference teaches that the hydrophilic colloids which contain SH-, NH₂-, NH=, -OH of polypeptide (refers to proteins of the instant claims). The reference clearly anticipates the claimed invention.

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 17-18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 3,148,187 and Jacobson et al., Federation Proceedings, vol. 42, No. 1, pages 72-79, January 1983 (Provided by applicants in the IDS filed on 11/13/02).

US Patent 3,148,187 teaches sulfonated cyanine and merocyanine dyes. The reference teaches nuclear sulfonated dyes. The reference teaches the nuclear sulfo-substituted dyes of the

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invention include cyanine dyes of formula I. The reference teaches the methods of sulfonating the cyanine dyes. The reference teaches that the sulfonated dyes are valuable for use in photography because of their good solubility in water (see column 6). The reference teaches the soluble dyes are prepared by direct nuclear sulfo nation of cyanine dyes. The reference teaches that the dyes prepared by the method are distinguished from the prior art dyes by having at least one sulfo group attaches to a nuclear carbon atom rather than a nitrogen atom in the heterocyclic ring (I.e., see column 6). The claimed invention differs from the prior art teachings by reciting that the 'component has at least one amino or hydroxy group which reacts with the cyanine dye.

US Patent 3,148,187 teaches cyanine dyes useful in photography. The reference recites water soluble cyanine dyes. The reference does not teach that the cyanine dyes are used in labeling biological compounds. However Jacobson et al discuss the application of fluorescence photo bleaching technique to cell biology. The reference discusses the advances in fluorescence photo bleaching. Jacobson et al teach that fluorescein isothiocyanate labeled actin (i.e., see page 74, right column). And further Jacobson et al review the work by Waggoner et al, in synthesis and characterization of cyanine-type fluorescent probes and use of the cyanine dyes in fluorescent dye labeling. The reference teaches that the cyanine dyes can be excited in deeper red region of the spectrum and can be conjugated to proteins (i.e., see page 77, middle column). The reference further teach the advantages of cyanine fluorescent dyes, which would reduce the detection limits because of less back ground fluorescence and minimal radiation damage to the cell. Thus, it would have been obvious to one skilled in the art at time the invention was made to use the water

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soluble cyanine dyes taught by US Patent 3,148,187 to label biological compounds such as actin. (All the biological compounds protein or nucleic acid have either and/or both amino or hydroxy group, which are known to be reactive). A person skilled in the art would have been motivated to use the water soluble cyanine dyes of US Patent 3,148,187 in labeling the biological compounds, because Jacobson et al teach fluorescence photo bleaching using cyanine dyes, and US Patent teaches the advantages of the water soluble cyanine dyes.

23. Claims 13-14, ¹⁶~~17~~-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 3,148,187 and Masuda et al (US Patent 4,404,289).

US Patent 3,148,187 teaches sulfonated cyanine and merocyanine dyes. The reference teaches nuclear sulfonated dyes. The reference teaches the nuclear sulfo-substituted dyes of the invention include cyanine dyes of formula I. The reference teaches the methods of sulfonating the cyanine dyes. The reference teaches that the sulfonated dyes are valuable for use in photography because of their good solubility in water (see column 6). The reference teaches the soluble dyes are prepared by direct nuclear sulfo nation of cyanine dyes. The reference teaches that the dyes prepared by the method are distinguished from the prior art dyes by having at least one sulfo group attaches to a nuclear carbon atom rather than a nitrogen atom in the heterocyclic ring (i.e., see column 6). The reference sulfonated cyanine dyes read on the cyanine dye of claim 13. The claimed invention differs from the prior art teachings by reciting that the component has at least one amino or hydroxy group which reacts with the cyanine dye.

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US Patent 3,148,187 teaches cyanine dyes useful in photography. The reference recites water soluble cyanine dyes. The reference does not teach that the cyanine dyes are used in labeling biological compounds. US Patent 4,404,289 (Masuda et al) teach methods in which a spectral sensitizer is employed as the photographically active substance are : 1) method for immunologically measuring the trace components which comprises antigen or antibody labeled with spectral sensitizers (i.e., see column 1). The reference teaches the advantages of the immunochemical method using spectral sensitizers. The reference discloses that the antigen or antibody (refers to protein) labeled with spectral sensitizers such as cyanine dyes of formula C or C' (i.e., see column 10). The reference teaches that the cyanine dyes contain at least one mercapto group, an amino group, hydroxy group or carboxy group in the heterocycle. The reference discloses that the disclosed spectral sensitizers are particularly advantageous as the labeling substances since these dyes are excellent in binding to the trace components such as antigen or antibody. The reference discloses the formula of the cyanine dye of formula C in columns 11-13. The reference teaches that the labeling of antigen or antibody with spectral sensitizers for photographic use is effected through a chemical reaction, that is the spectral sensitizer is introduced into the antigen or antibody via a covalent bond. The reference teaches that it is preferred that the spectral sensitizer and the antigen or antibody contain an amino group, a mercapto group, hydroxy group capable of reacting with such group.

Thus it would have been obvious to one skilled in the art to use the water soluble cyanine dyes taught by the reference taught by the US Patent 3,148,187 with the method of labeling

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antigen or antibody taught by US Patent 4,404,289 because the '187 teaches the advantages of the water soluble sulfonated cyanine dyes and the '289 teaches the advantages of the use of spectral sensitizers in labeling the antigen or antibody. A person skilled in the art would have been motivated to obtain the cyanine dye labeled compounds such that labeled compounds are useful in diagnostic assays which would enable one to reduce the quantity of a testing sample required for improved detection sensitivity and thus enables multiple test samples.

24. No claims are allowed.

25. Applicant's submission of an information disclosure statement under 37 CAR 1.97© with the fee set forth in 37 CAR 1.17(p) on 11/13/02 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(I). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Primary Examiner
Technology Center 1600
Art Unit 1639
11 March 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER